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| 08/460,715      | 06/02/1995  | MICHAEL MACH         | 5552.0738-02        | 5690             |

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EXAMINER

WORTMAN, DONNA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1648

DATE MAILED: 06/11/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

08/460,715

Applicant(s)

MACH ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 March 2003 and 09 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7,8,37,39,41-43,45-52,55-60 and 62-86 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37,39,62 and 63 is/are allowed.
- 6) ☒ Claim(s) 41-43,45-52,55-60 and 64-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 7,8,37,39,41-43,45-52,55-60 and 62-86 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 37, 39, 45, 50, and 52 were amended, claims 44, 53, and 61 were canceled, and claims 62-72 were added in Paper No. 35 filed March 18, 2003. Claims 41-43, 45-52, 55-60 and 64-72 were amended, claims 19, 21, and 54 were canceled, and claims 73-86 were added in Paper No. 36 filed April 9, 2003. Claims 7 and 8 are pending but withdrawn from consideration as drawn to a non-elected invention. Claims 37, 39, 41-43, 45-52, 55-60, and 62-86 are pending and under examination.

Rejections withdrawn or rendered moot

The rejections of claims 37, 39, 45, 50 and 58 under 35 U.S.C. 112, second paragraph, as set out on page 5 of Paper No. 32 is withdrawn in view of the amendments to the claims in Paper No. 35.

The rejection of claims 44, 53, and 61 under 35 U.S.C. 112, second paragraph, as set out on page 5 of Paper No. 32 is moot in view of the cancellation of these claims in Paper No. 35.

The rejection of claims 44, 53, and 61 under 35 U.S.C. 112, first paragraph, as set out on page 3 of Paper No. 32 is moot in view of the cancellation of these claims in Paper No. 35.

The rejection of claims 19, 21, and 54 under 35 U.S.C. 112, first paragraph, as previously offered at page 2 of Paper No. 32 is moot in view of the cancellation of these claims in Paper No. 36.

The rejection of claims 19, 21, 54, 41-43, 48, 49, and 55-57 as set out at page 2 of Paper No. 32 is moot with respect to claims 19 and 21 in view of the cancellation of these claims in Paper No. 36, and is withdrawn for claims 54, 41-43, 48, 49, and 55-57

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in view of Applicant's amendments to the claims, addition of new claims, and remarks at page 7, line 6-page 8, line 11; and page 8, line 18-page 9, line 1.

New objections

Claims 81 and 85 are objected to because of the following informalities:

In claim 81, "*E. Coli*" should read "*E. coli*."

In claim 85, "eukaryotic" is misspelled.

Appropriate correction is required.

New rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73, 77-79, 74, 41-43, 45-47, 64-66, 75, 80, 81, 76, 48-52, 67-69, 82, 84-86, 83, 55-60, and 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 73, 74, 75, 76, 82 and 83 are unclear because they refer to recombinant DNA or vectors as "comprising HCMV pp28"; pp28 is the name of a viral protein and not the name of the DNA that encodes it. It is suggested that the term "gene" and/or the word "encoding," e.g., be employed in order to clarify the claim language with respect to the DNA recited and the protein encoded by the DNA.

Claims 77-79, 81, 84-86, and 55-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support could be located in the specification for the following specific embodiments of newly claimed subject matter:

Claim 77, bacteriophage prokaryotic expression vector that expresses the entire HCMV pp28 in prokaryotic cells.

Claim 78, lambda phage prokaryotic expression vector that expresses the entire HCMV pp28 in prokaryotic cells.

Claim 79, prokaryotic expression vector that expresses the entire HCMV pp28 in prokaryotic cells and encodes a fusion protein.

Claim 81, *E. coli* prokaryotic cell transformed with DNA comprising entire HCMV pp28.

Claim 84, eukaryotic cell which is a fibroblast transformed with a recombinant DNA comprising the entire HCMV pp28 [gene] and that expresses the entire HCMV pp28.

Claim 85, eukaryotic cell which is a human fibroblast transformed with a recombinant DNA comprising the entire HCMV pp28 [gene] and that expresses the entire HCMV pp28.

Claim 86, eukaryotic cell which is a human cell transformed with a recombinant DNA comprising the entire HCMV pp28 [gene] and that expresses the entire HCMV pp28.

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Claim 55, eukaryotic cell which is a fibroblast transformed with a recombinant DNA comprising [DNA that encodes] an antigenic portion of HCMV pp28 and that expresses the antigenic portion of HCMV pp28.

Claim 56, eukaryotic cell which is a human fibroblast transformed with a recombinant DNA comprising [DNA that encodes] an antigenic portion of HCMV pp28 and that expresses the antigenic portion of HCMV pp28.

Claim 57, eukaryotic cell which is a human cell transformed with a recombinant DNA comprising [DNA that encodes] an antigenic portion of HCMV pp28 and that expresses the antigenic portion of HCMV pp28.

It is noted that the specification discloses prokaryotic and eukaryotic vectors and cells broadly, and specific prokaryotic vectors and cells within the context of expressing antigenic portions of HCMV pp28, but does not disclose particular eukaryotic cell types for any pp28 expression, nor the combination of specific prokaryotic vector and cell types for expressing the entire pp28. The only mention of specific eukaryotic cell types that could be located is the use of human fibroblast cells to grow HCMV in order to prepare the viral DNA (specification, page 2, lines 9-14). Applicant is invited to point out any other support that may be applicable.

Claims 37, 39, 62 and 63 are allowed. The prior art does not teach or fairly suggest producing and selecting the claimed restriction fragments that encode an antigenic portion of HCMV pp28. The claims are interpreted to encompass restriction fragments as claimed from HCMV strains that have the recited restriction fragments that

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encode an antigenic portion of HCMV pp28, as pointed out in the Interview Summary dated March 25, 2003, and designated as Paper No. 33.

This application contains claims 7 and 8 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

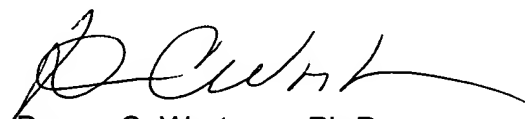
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw  
June 10, 2003